IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES LLC AND EDWARDS LIFESCIENCES PVT, INC.,	)	
Plaintiffs	)	
v.	)	C.A. No. 12-023-GMS
MEDTRONIC COREVALVE LLC, MEDTRONIC CV LUXEMBOURG S.A.R.L., MEDTRONIC VASCULAR GALWAY LTD., MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,	)	
Defendants.	)	

MEDTRONIC'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR A NEW TRIAL OR ALTERNATIVELY TO AMEND OR ALTER THE JUDGMENT

OF COUNSEL:
Martin R. Lueck
Jan M. Conlin
Stacie E. Oberts
Munir R. Meghjee
Andrew D. Hedden
ROBINS, KAPLAN, MILLER & CIRESI LLP
2800 LaSalle Plaza
Minneapolis, MN 55402
(612) 349-8500

Edward R. Reines
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065
(650) 802-3000

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
David M. Fry (No. 5486)
SHAW KELLER LLP
300 Delaware Avenue, Suite 1120
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
dfry@shawkeller.com
Attorneys for Medtronic CoreValve LLC, Medtronic CV Luxembourg S.a.r.l., Medtronic Vascular Galway Ltd., Medtronic, Inc., and Medtronic Vascular, Inc.

Dated: February 12, 2014

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

Cases

Statutes

Rules

I. INTRODUCTION

If the Court declines to grant Medtronic's Renewed Motion for Judgment as a Matter of Law ("JMOL Motion"), Medtronic asks the Court to grant a new trial. As explained in detail below, and in Medtronic's Opening Brief in Support of Its JMOL Motion, incorporated herein by reference, the Court made errors in both its instructions to the jury as well as in its exclusion of highly relevant evidence.

II. ARGUMENT

A. If the Court Does Not Grant Medtronic's Renewed JMOL Motion, Medtronic Requests a New Trial Because the Verdict Was Contrary to the Clear Weight of the Evidence.

A new trial is proper under Fed. R. Civ. P. 59, even if substantial evidence supporting the verdict may bar judgment as a matter of law, where "the verdict was against the weight of the evidence . . . [and] a miscarriage of justice would result if the verdict were to stand." *Williamson v. Consol. Rail Corp.,* 926 F.2d 1344, 1352 (3d Cir. 1991). On a new trial motion, the Court need not presume that the verdict was correct; nor need it view the evidence in the light most favorable to the party in whose favor the verdict was rendered. *Belden Techs. Inc. v. Superior Essex Commc'ns LP*, 802 F. Supp. 2d 555, 562 (D. Del. 2011). Where the trial "deals with a subject matter not lying within the ordinary knowledge of jurors a verdict should be scrutinized more closely by the trial judge than is necessary where the litigation deals with material which is familiar and simple." *Lind v. Schenley Inds., Inc.*, 278 F.2d 79, 90-91 (3d Cir. 1960).

As set forth more fully in Medtronic's Opening Brief in Support of Its Renewed Motion for Judgment as a Matter of Law, Medtronic requests that the Court grant a new trial because the verdict was against the clear weight of the evidence in the following ways:

1. The jury's conclusion that the CoreValve device is capable of being delivered through an arterial introducer that is 5.7 mm or less into a patient's vasculature

using a catheterization technique is contradicted by the fact that the CoreValve device cannot be delivered through an introducer that is less than 6.0 mm.

2. The jury's conclusion that the CoreValve frame "resists the recoil force exerted by the stenosed aortic valve" cannot stand since there is no recoil generated during implantation of the CoreValve device. Edwards utterly failed to introduce any evidence to prove this limitation was met.

3. The jury's conclusion that the shipment of pericardial sacs from the United States satisfies the requirements of § 271(f)[1] is in contradiction with the express requirements of the statute because: (1) there must be more than one component supplied from the United States; (2) Edwards admitted that the pericardial sac is not "combined" into the accused product; and (3) Edwards admitted that fixed porcine pericardial tissue has other uses besides the CoreValve device.

4. The jury's conclusion that the asserted claims were enabled is contradicted by the overwhelming evidence from Dr. Cribier that he did not know how to make, nor did his patent teach how to make, a frame that was compressible to 5.7 mm or less, as well as Dr. Buller's admission that the patent did not enable a device that could be compressible to 10 French.

5. The jury's conclusion that the asserted claims satisfy the written description requirement is contradicted by Dr. Cribier's testimony that a self-expanding device would not meet the requirements of his invention, as well as that there is no description of only a frame being compressible to 5.7 mm or less.

[1] With respect to Edwards' claim under § 271(f)(1), the Court refused to instruct the jury on active inducement, as set forth in detail in Medtronic's Opening Brief for JMOL, which also warrants a new trial.

6. The jury's conclusion that the asserted claims are not obvious is contradicted by the fact Dr. Buller admitted that all of the limitations of the asserted claims, aside from the internal cover, were disclosed in Andersen coupled with Dr. Buller's admission that internal and external covers were well known.

7. The jury's conclusion that Medtronic willfully infringed is contradicted by Medtronic's objectively strong defenses to Edwards' allegations.

8. The damages verdict lacks substantial evidence and fails as a matter of law.

B. A New Trial Should Be Granted Because Jury Instruction 3.2, Regarding the Construction of "Frame," Was Erroneous and Prejudicial.

A new trial is the appropriate remedy where a jury instruction was erroneous and prejudicial. *Hill v. Reederei F. Laeisz G.M.B.H.,* 435 F.3d 404, 424 (3d Cir. 2006). Over Medtronic's objection, the Court gave the following instruction regarding "frame":

> The term "frame" as used in Claims 1 and 2 is construed to mean "a circumferential stent structure." The term "frame" does not include any material other than the circumferential stent structure.

Jury Instruction 3.2. The Court allowed Edwards to add the last sentence despite the fact that Edwards never raised this issue during the *Markman* proceedings. In fact, during the charge conference, the Court indicated that it allowed this change as a "sanction[]." Tr. 1287-88. Not only did Medtronic **do nothing** to warrant any sanction, the Court did not follow the procedures necessary to impose any such sanction. A review of the proceedings demonstrates that it was **Edwards** that raised an untimely claim construction. Medtronic has consistently applied this Court's construction since it issued on April 23, 2013.

As fully set forth in Medtronic's Opening Brief in Support of Its JMOL Motion, the Court's instruction regarding "frame" enabled Edwards to rely upon an infringement theory that

this Court recognized as apparently "erroneous and misguided." *See* D.I. 139 at 2 n.2. If the Court does not enter judgment as a matter of law, then a new trial is the appropriate remedy.

C. A New Trial Should Be Granted to Correct the Exclusion of Evidence that the CoreValve with the Tissue Valve and Skirt Cannot Fit into an Introducer that Is 5.7 mm or Less for Introduction into a Patient's Vasculature Using a Catheterization Technique.

The Court prohibited Medtronic from presenting testimony and evidence showing that the CoreValve cannot meet the claim requirement of a "frame being compressible to a compressed external diameter capable of being introduced through an 18 French arterial introducer and into a patient's vasculature using a catheterization technique," because the CoreValve frame with the tissue valve and skirt cannot be introduced through an arterial introducer that is less than 6.0 mm. Tr. 3:1-18:8.

The Court's stated reason for the exclusion is based on its erroneous conclusion that Medtronic's non-infringement defense was an untimely claim construction issue. As explained in Medtronic's Opening Brief in Support of Its JMOL Motion, however, Medtronic was actually applying this Court's construction of "18 French" which clearly related to the entire prosthetic valve assembly.

As the Third Circuit has made clear, "the exclusion of critical evidence is an 'extreme' sanction, not normally to be imposed absent a showing of willful deception or 'flagrant disregard' of a court order by the proponent of the evidence." *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 905 (3d Cir. 1977) (citations omitted), *overruled on other grounds by Goodman v. Lukens Steel Co.,* 777 F.2d 113 (3d Cir. 1985). In determining whether exclusion is appropriate, the court must consider whether: (1) "the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified" or the excluded evidence would have been offered; (2) "the ability of that party to cure the prejudice"; (3) the extent to

which allowing such witnesses or evidence would "disrupt the orderly and efficient trial of the case or of other cases in the court"; (4) any "bad faith or willfulness in failing to comply with the court's order"; and (5) the importance of the excluded evidence. *ZF Meritor, LLC v. Eaton Corp*., 696 F.3d 254, 298 (3d Cir. 2012) (quoting *Pennypack*, 559 F.2d at 904-05) (reversing exclusion of expert testimony). "The importance of the evidence is often the most significant factor." *Id*.

Here, Medtronic **did not** raise an untimely claim construction—Edwards did. Even if it did, however, the Third Circuit has made clear that untimeliness alone does not justify exclusion. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 792 (3d Cir. 1994) (discussing two cases in which the Third Circuit reversed exclusion as an abuse of discretion, noting that in the first case, "the defendant . . . did not make the plaintiffs aware of the exact substance of the testimony until *trial*[,]" and in the second case, "the substance of the testimony was revealed far closer to trial than it was here (three weeks before trial)") (citing *DeMarines v. KLM Royal Dutch Airlines*, 580 F.2d 1193, 1202 (3d Cir. 1978); *Pennypack*, 559 F.2d at 905)).

There was no basis to preclude Medtronic from entering evidence that clearly shows—as a matter of law—that the CoreValve cannot infringe any of the asserted claims. The importance of the excluded evidence cannot be more evident—it proves, without a doubt, that Medtronic does not infringe the asserted claims of the '825 patent.

If the Court does not enter judgment as a matter of law, Medtronic requests a new trial.

D. A New Trial Should Be Granted to Correct the Exclusion of Evidence Regarding Edwards' Factual Admissions in Foreign Proceedings.

Edwards has made factual admissions regarding the CoreValve device and the scope of Dr. Cribier's invention in litigation in Germany and before the European Patent Office that are directly contrary to the positions it advanced at trial. These prior proceedings involve the same

parties, the same accused product, and patents from the same inventors that claim priority to the same European patent and have similar language as the asserted claims of the '825 patent.

First, in Germany, a three judge panel found the CoreValve device does not infringe the '825 patent's counterpart based on **facts admitted by Edwards**—specifically, that the CoreValve device cannot fit through a 5.7 mm introducer. The panel stated: "The arguments in the briefs of **the parties agree** in the assumption that **a catheter with an external diameter of 6 mm is necessary** for the opposed prosthetic valve assembly." D.I. 145, Ex. 1 at 15 (emphasis added). Edwards' own testing showed the CoreValve's diameter was 5.95 mm. *Id.* The panel found "[a]n external diameter of 5.95 mm – in the case of a claimed external diameter of not more than 5.7 mm – lies outside the scope of protection of the patent." *Id.* These admissions prove the CoreValve device does not infringe the asserted claims and thus are highly probative.

In addition, since a German court found that Medtronic did not infringe claims that require an arterial introducer that is 5.7 mm or less—the same non-infringement argument Medtronic advanced in this case—the decision is relevant to rebut Edwards' willful infringement claim. Evidence of related prior litigation is admissible to assist the fact finder in deciding the issue of willfulness. *See Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 435 F.3d 1356, 1366 (Fed. Cir. 2006); *Mendenhall v. Cedarapids, Inc.,* 5 F.3d 1557, 1573 (Fed. Cir. 1993) ("Defendants' knowledge of the prior litigation would also be relevant to the allegation of willful infringement."). Decisions by foreign courts are admissible as well for purposes of rebutting a claim of willfulness. *BIC Leisure Prods. v. Windsurfing Int'l*, 1 F.3d 1214, 1223 (Fed. Cir. 1993). In *Applied Medical,* the plaintiff had previously prevailed in a patent suit targeting the defendant's trocar product, a medical device used during laparoscopic surgery. 435 F.3d at 1358. The defendant then redesigned its product and resumed its sales, and the plaintiff sued again.

During the second trial, the district court permitted the introduction of evidence regarding the outcome of the first suit, including the jury's finding of willful infringement. *Id.* at 1365-66. The Federal Circuit affirmed, holding that the prior litigation "was relevant to the jury's willfulness determination" as well as to the reasonable royalty analysis. *Id.* It also concluded that the evidence's probative value was not outweighed by the danger of unfair prejudice, and that the prior verdict was therefore admissible. *Id.*

As with the prior verdict in *Applied Medical,* Medtronic's success in defending against litigation brought by Edwards on the Cribier patent is highly probative evidence for both prongs of the *Seagate* willfulness analysis. *See In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007). First, that decision undermines any suggestion that there was an "objectively high risk" that the CoreValve device infringed the '825 patent. The jury should have been afforded the opportunity to weigh the fact that a German court previously determined that the CoreValve device does not infringe because the outside diameter of the CoreValve is 6.0 mm and thus cannot fit through an arterial introducer that is 5.7 mm or less, as it was assessing the first, objective prong of *Seagate*. Second, the German decision disproves any assertion that Medtronic knew or should have known that it was "highly likely" it was infringing the '825 patent.

Second, in the EPO proceeding, a number of medical device manufacturers, including Medtronic, challenged the validity of the Cribier counterpart '115 patent. In response, **Edwards admitted** to the EPO that the compressibility relates to the entire device, not just the frame. Edwards admitted "**that the frame is compressible to an external diameter does not mean anything else than that in fact the <u>entire prosthetic valve assembly</u> is compressible to said diameter**." D.I. 135, Ex. 2 at ¶ 42 (emphasis added). This admission is completely contrary to the position Edwards advanced before the jury—that the claim only requires the frame to be

compressible, and **not** the entire prosthetic valve assembly. The Federal Circuit has explicitly recognized that representations to a foreign patent office regarding how one of skill in the art understands claim language in a foreign counterpart are relevant in proceedings involving U.S. patents. *Tanabe Seiyaku Co. v. United States ITC*, 109 F.3d 726, 733 (Fed. Cir. 1997); *see also Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1374 (Fed. Cir. 2005) ("This blatant admission by this same defendant before the EPO clearly supports this court's holding . . . ."). Medtronic should have been allowed to cross examine Dr. Buller's assertions regarding the scope of the claim with the very admissions that Edwards made to the European Patent Office.

Edwards' admissions before these two legal bodies not only establish the reasonableness of Medtronic's non-infringement defense here, but they in fact establish that the CoreValve device does not infringe the '825 patent. The Court erred in declining to admit this critical evidence and Medtronic requests a new trial.

E. A New Trial Should Be Granted to Correct the Exclusion of Evidence that the Asserted Claims Are Not Enabled Because There Is No Teaching of How to Build a Prosthetic Valve, Including the Frame, Valvular Structure and Internal Cover, that Could Be Compressible to Be Delivered Through an Arterial Introducer that is 5.7 mm or Less.

The Court also improperly prevented Medtronic from introducing evidence on enablement based on Edwards' "erroneous and misguided" construction that only the frame need be compressible for delivery through an introducer with a diameter of 5.7 mm or less. But the asserted claims are comprising claims, and therefore a stent that is compressible to 5.7 mm or less with tissue sewn inside would still be within the scope of the claims. Such a device must therefore be enabled for the full scope of the claims to be enabled.

At Edwards' urging, however, the Court precluded Medtronic from introducing evidence that such a device was not enabled. During cross examination of Dr. Cribier, Edwards argued to the Court that "the enablement question shouldn't make your patent invalid because you didn't

enable a complete device that's compressible to 5.7." Tr. 327:16-18. Edwards' assertion is contrary to the law: "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997).

Even under Edwards' construction, a device in which the frame with the tissue sewn inside is compressible to a collapsed external diameter capable of introduction through an introducer with a diameter of 5.7 mm or less is within the scope of the claims. Evidence that such a device is not enabled is therefore relevant to the validity of the asserted claims. The Court's ruling, based on Edwards' misrepresentation of the law, precluding Medtronic from presenting such evidence was erroneous and highly prejudicial. A new trial should be granted.

F. A New Trial Should Be Granted to Correct the Court's Decision to Preclude Medtronic from Explaining in Closing Arguments that the Patent Does Not Enable the Full Scope of the Claims.

The jury was instructed that if the inventors fail to teach how to practice the full scope of the invention, the claims are invalid. Jury Instruction 4.2. The enablement requirement "prevents both inadequate disclosure of an invention and overbroad claiming that might otherwise attempt to cover more than was actually invented." *MagSil Corp. v. Hitachi Global Storage Techs.*, 687 F.3d 1377, 1381 (Fed. Cir. 2012). "Thus, a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage." *Id.*

Despite that instruction, the Court prevented Medtronic from discussing during closing arguments that the evidence established that the patent does **not enable the full scope of the claim**. Tr. 1350. The '825 patent broadly claims prosthetic valves where the frame is "compressible to a compressed external diameter capable of being introduced through an 18 French arterial introducer." The plain language of the claim contains no lower limit. This is confirmed by the fact that there are two claims that depend from claim 1 that recite 16 French

and 14 French arterial introducers. Claim 1, therefore, necessarily includes lower ranges within its scope.

The Court's construction also does not include a lower limit. That construction was based in part on the patentee's express statement to the Patent Office to overcome prior art: "there was 'no teaching or suggestion in the cited references' regarding a prosthetic valve assembly that included a stent, a valvular structure[,] and an internal cover, where the entire assembly was collapsible to a diameter of '**5.7 mm or less** for advancement through an introducer and into a patient's vasculature via a catheterization technique.'" D.I. 103 at 4 n.4.

Both Dr. Cribier and Dr. Buller admitted that the claims are not enabled below a certain point. First, Dr. Cribier testified that 14 French "was the best that I could hope would be possible to make." Tr. 317:25-318:4. Dr. Buller also admitted that the claims are not enabled:

> Q. Can one of ordinary skill in the art, as of December 31 of 1996, make and use the invention claimed in Claim 1 armed with the patent specification and the knowledge of one skilled in the art with a device that is at 10 French?
>
> A. No, I don't believe they could make one and enable it at 10 French for the whole claim, for everything in the claim.

Tr. 655:4-10. Dr. Buller also agreed that there are devices compressible to 3 French that can be put into the vasculature, and that the asserted claims do not have a lower limit. Tr. 649:16-20, 656:20-21. Edwards' own witnesses have thus **admitted** that the patent does not enable the **full scope** of the claim—either 5.7 mm **or less**.

The testimony of Drs. Cribier and Buller was presented to the jury without objection. Yet at Edwards' urging, Medtronic was precluded from arguing during closing that the claims were invalid based on this admitted failure to enable the full scope of the claim, which was improper.

Edwards' assertions of surprise and prejudice are meritless, and flatly at odds with its agreement to include that very language in the jury instruction. D.I. 125, Exhibit O (Part II) at 49. It is also inconsistent with Edwards' agreement that the purpose of the enablement requirement is to ensure that the public "obtains from the inventor a full disclosure of how to make and use the full scope of the invention." Tr. 1297:20-1298:4 ("[T]he full scope of the claimed invention is required. You need to teach others how to practice that full scope."). This alone should have resolved this debate.

None of the grounds Edwards advanced for exclusion justified precluding Medtronic from raising this admitted failure to enable the claims during closing argument. *See* D.I. 158.

First, invalidity is not based on the inclusion of "or less" in this Court's construction. Instead, **Claim 1 as issued includes a range**, as dependent claims 8 and 9 make clear. Claim 1 covers all devices "capable of delivery through an 18 French arterial introducer," which necessarily includes devices capable of delivery through a 16 French arterial introducer, a 14 French arterial introducer, or a 10 French arterial introducer.

Edwards itself presented evidence that relied on a range of sizes, both in the context of infringement and validity. Edwards relied on Medtronic's statements to the FDA that testing had been performed on frames crimped to diameters of 4.75 mm, 5.46 mm, and 5.5 mm.[2] *See, e.g.*, D.I. 167-3 at 10. Dr. Buller also testified that whole devices "back in the 1980s" could be "collapsed down and fit into a 12 French catheter." Tr. 495:11-496:2. Edwards relied on these prior art devices as evidence that the stent limitations of the asserted claims were enabled.

[2] Critically, none of these statements prove that Medtronic's device has been, or is capable of being, introduced through an introducer with a diameter of 5.7 mm or less because they are not measurements of the device as it is delivered using Medtronic's catheterization technique.

Second, Edwards' contention that Medtronic had not previously raised the defense is sheer revisionist history. Medtronic raised the enablement defense in its initial disclosures, noting "in particular" that the patent did not enable the "full scope of the claim." D.I. 160, Ex. A at 5. Medtronic's expert then opined that regardless of how the Court ultimately construes the claim, the "18 French" limitation was not enabled because the inventors had no idea how to build a frame that could compress that small. D.I. 160, Ex. C at 3, 53-54, 59. Dr. Loomis highlighted Dr. Cribier's testimony that "probably the engineers will be able to make something like this 18 French, 16 French. Why not 14 French? . . . But at that time it was just a dream . . . ." *Id.* at p. 54.

Medtronic then cited the *MagSil* case in its April 22, 2013 letter to the Court, noting "the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention." D.I. 102 at 1. In its trial brief, Medtronic again explained that the '825 patent does not describe "the benefits of small diameter introducers, or how to actually build a prosthetic valve with an internal cover that could be introduced through them [small diameter introducers]." D.I. 125, Ex. N at 11. The failure of the patent to enable "small diameter introducers" was unmistakably part of Medtronic's enablement defense.

There is no cognizable prejudice to Edwards. Both Drs. Cribier and Buller admitted before the jury—without objection—that the full scope of the claims is not enabled. Edwards' contention that Medtronic's expert did not address this failure is both incorrect, and more importantly, immaterial. The evidence did not come in through Medtronic's expert. It was Edwards' own witnesses that testified to the lack of enablement.

"[T]he exclusion of critical evidence is an 'extreme' sanction, not normally to be imposed absent a showing of willful deception or 'flagrant disregard' of a court order by the proponent of the evidence." *Pennypack*, 559 F.2d 894 at 905 (citations omitted). No such showing was or

could be made here, and it was erroneous and highly prejudicial to preclude Medtronic from discussing this evidence during closing. If judgment as a matter of law is not entered, then a new trial should be granted.

G. A New Trial Should Be Granted to Correct the Exclusion of Evidence that Shows Undue Experimentation.

"To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Alza Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010) (quoting *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997)).

Dr. Cribier's experience in attempting to make a valve that could be introduced through an 18 French arterial introducer is relevant to enablement. Dr. Cribier agreed that "the patent does not tell you how to build a valve **stent** to a size that can be compressed for delivery through an 18-French introducer." Tr. at 335:22-25 (emphasis added). Instead, Dr. Cribier relied on engineers: "I am not able myself to make a stent because I am not an engineer. So the interest of working with a company like JJIS was to have the benefit the experience of the JJIS engineers . . . ." Tr. 258:1-6. Dr. Cribier agreed, however, that his work with Johnson & Johnson "was basically a complete failure." Tr. 339:8-19. Dr. Cribier therefore turned to another group of engineers, ARAN. Tr. at 309:6-310:5.

But the ARAN engineers, despite working directly with Dr. Cribier, were unable to build a device that could be delivered **through** an 18 French introducer for over a decade. *See, e.g.*, Ex. A, Dep. Design. of Assaf Bash; DTX 5; DTX 11; DTX 25; Ex. B, Dep. Design. of Stan Rowe; DTX 33. These repeated failures demonstrate undue experimentation and are highly relevant to the question of enablement of the asserted claims.

Edwards convinced the Court to exclude this probative evidence because the SAPIEN that resulted from this lengthy **experimentation** does not practice the asserted claims. D.I. 131 at 56-61. The complete failure to build **any** valve capable of satisfying the stent limitations of the asserted claims makes it more probable that the claims as a whole were not enabled, and evidence of that failure is directly relevant on the issue of validity.

The exclusion of this evidence was highly prejudicial and necessitates a new trial.

H. A New Trial Should Be Granted to Correct the Exclusion of Evidence that Shows Continued Access Sales Are Exempt From Infringement.

The Court precluded Medtronic from offering evidence showing that continued access sales are exempt from infringement, and thus cannot be subject to damages. The Court's decision was based on Edwards' argument that Medtronic had waived the argument. Tr. 423:10-425:12. The facts show, however, that Medtronic never waived its argument that continued access sales are exempt from infringement. First, the safe harbor of 35 U.S.C. § 271(e)(1) is an **exemption** to patent infringement, and, thus, is not required to be affirmatively pled. *Integra Lifesciences I, LTD. v. Merck KGaA*, 331 F.3d 860, 866 n.3 (Fed. Cir. 2003).

But even if it were an affirmative defense, the Federal Circuit has recently held that where a party has had adequate notice that the other party was raising a particular defense, it is improper to exclude that defense. *Pac. Coast Marine Windshields Ltd. v. Malibu Boats, LLC*, 739 F.3d 694, 701 n.4 (Fed. Cir. 2014). There can be no dispute that Edwards was on notice that it was Medtronic's position that continued access sales are not subject to damages. Medtronic provided a 30(b)(6) witness specifically on the topic of continued access sales. D.I. 156 at 1 n.1. Then, on March 15, 2013—almost a full year before trial—Medtronic's expert unequivocally stated that continued access sales are exempt:

> Further, it is my understanding that these Continued Access sales, as well as other sales "reasonably related to the development and submission of

> information" to the FDA are covered under the "safe harbor" exemption of 35 U.S.C. § 271(e), and, therefore, should not be considered for either lost profits or reasonable royalty damages.

D.I. 156, Ex. E, ¶ 81. Medtronic raised the same argument in its trial brief. D.I. 125, Ex. N at 14.

Edwards' assertions of surprise and prejudice ring hollow—it has long known Medtronic's position regarding continued access sales. Edwards **admitted** in its trial brief that Medtronic had raised the safe harbor exemption. D.I. 125, Ex. M at 5. Edwards' trial brief establishes that it fully intended to rebut Medtronic's assertion of the safe harbor exemption based on evidence to be presented at trial. *Id.* at 10-11 ("Medtronic argues that certain conduct is exempted from infringement under the 35 U.S.C. § 271(e)(1) safe harbor. . . . Edwards **will show** that Medtronic is incorrect. . . . Edwards **will show** that Medtronic has commercialized its CoreValve system . . . .") (emphases added).

Continued access sales are exempt from infringement under the broad statutory safe harbor of § 271(e)(1). *See* D.I. 156 at 2. Because Medtronic did not waive this argument, it was highly prejudicial to preclude Medtronic from introducing evidence and argument that Edwards was not entitled to $40.1 million of its requested damages based on the continued access sales. Accordingly, if the Court denies Medtronic's JMOL on the issue of continued access sales, a new trial is necessary.

I. Medtronic Requests Remittur, or Alternatively a New Trial on Damages, to Correct the Unsubstantiated Damages Theories Presented by Edwards.

The damages theories presented by Edwards are unsubstantiated and legally unsound. The jury failed to follow this Court's instruction that:

> Only the profits lost by the named plaintiffs, Edwards Lifesciences LLC or Edwards Lifesciences PVT Inc., can be recovered. Edwards may not be compensated for lost profits of any of their affiliates or subsidiaries.

Jury Instruction 5.6. Accordingly, Medtronic requests remittitur.

If the Court refuses to grant remittitur, a new trial is necessary since Edwards' unsubstantiated damages theories were highly prejudicial to Medtronic. The prejudicial effect is exemplified by the fact that the jury awarded $388 million in lost profits even though Edwards was only allowed to request $285 million in closing. Tr. 1350:22-1351:15. Edwards' presentation of such theories improperly skewed the damages horizon, necessitating remittitur or a new trial on damages. *See, e.g., Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1320 (Fed. Cir. 2011) ("The disclosure that a company has made $19 billion dollars in revenue from an infringing product cannot help but skew the damages horizon for the jury . . . .").

1. The Court should amend the judgment by reducing the damages award by $103 million which are not lost profits of any named party.

The Court should reduce the award by $103 million which are not lost profits of any named plaintiff. The Court already determined that Edwards is not entitled to lost profits made by non-named Edwards' subsidiaries. Tr. 1350:22-1351:15. The effect of the Court's ruling was to reduce Edwards' maximum lost profits damages request from $388 million to $285 million. *Id.*; Tr. 1464:18-23. Despite that fact, the jury failed to follow the Court's instructions and awarded Edwards $388 million in lost profits. D.I. 170 at 9. The Court should amend the judgment by reducing the damages award by $103 million.

2. The Court should amend the judgment by reducing the damages by $107 million because Edwards did not prove infringement pursuant to Section 271(f).

Medtronic's shipment of porcine pericardial tissue from the United States is not an act of infringement under 35 U.S.C. § 271(f). Edwards' expert testified that $107 million of Edwards' damages request was based on shipment of porcine pericardial sacs from the United States to Mexico. Tr. 844:19-845:2. If the Court grants Medtronic's motion for judgment as a matter of law, it should reduce the damages award by $107 million.

3. The Court should alter or amend the judgment to remedy any overlap of damages from previous litigation between the parties.

The current litigation involves the same CoreValve device that is at issue in *Edwards Lifesciences AG v. CoreValve, Inc.*, No. 08-91-GMS (D. Del.) ("Andersen"). Here, Edwards sought damages, including lost profits, for Medtronic's manufacture and sale of the CoreValve system since August 23, 2011. *See, e.g.*, Tr.765:18-20. But, based on a jury award obtained in Andersen, Edwards is simultaneously seeking damages for sales over that same time period.

Edwards cannot recover lost profits on the same sales of an identical product in two different actions. Lost profits recovery requires a showing by the patentee that "'but for' the infringement, it would have made the sales that were made by the infringer." *RiteHite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995). Availability of lost profits depends not on whether the '552 patent or the '825 patent is asserted, but instead examines the relevant market and the parties' capabilities. *See Crystal Semiconductor Corp. v. Tritech Microelectronics Int'l*, 246 F.3d 1336, 1357 (Fed. Cir. 2001) ("Lost profit damages do not depend on the number of patents infringed by one single product in the present case.").

Edwards agrees that it may not be awarded lost profits for the same sales in the two different cases. In its trial brief, Edwards said it sought to "avoid any issues of double counting damages and a duplicative jury award." D.I. 125, Ex. M at 12. Edwards also stated at the pretrial conference that it "does not intend to attempt to recover twice for lost profits." D.I. 131 at 7. It remains, however, that an overlap exists between the damages currently included in the judgment entered by the Court here, and the damages Edwards continues to seek in Andersen.

To date, however, the extent of overlap cannot be procedurally determined until Andersen is fully resolved. In Andersen, Edwards has filed a request for an accounting that seeks lost profits damages through May 1, 2012. *Edwards Lifesciences AG v. CoreValve, Inc.*, C.A.

No. 08-91-GMS, D.I. 463 (D. Del. Apr. 24, 2013). Medtronic has filed objections to portions of Edwards' post-trial damages calculations, including portions for the period February 8, 2011 through May 1, 2012. *Edwards Lifesciences AG v. CoreValve, Inc.*, C.A. No. 08-91-GMS, D.I. 485 (D. Del. May 10, 2013). The Court has not yet ruled on Medtronic's objections. This accounting necessarily includes sales for which lost profits have also been awarded in the current action. Any sales between August 23, 2011 and May 1, 2012 that are ultimately included in an accounting in Andersen must be deducted from the lost profits awarded in the current litigation.

Additionally, if the Court awards damages after May 2, 2012 in Andersen, that too will need to be deducted from the damages award here. The Andersen patent expired on May 2, 2012, but Edwards has sought a patent term extension, and is seeking an accounting based on its requested extension. *Edwards Lifesciences AG v. CoreValve, Inc.*, C.A. No. 08-91-GMS, D.I. 457 (D. Del. Apr. 24, 2013). Medtronic disagrees that the CoreValve falls within the scope of any patent term extension, and thus disputes that any post-May 1, 2012 activity is subject to a damages award in Andersen. In the event, however, that manufacture or sale in the United States of the CoreValve device after May 2, 2012 is subject to an accounting in Andersen, then those damages must also be deducted from any final award in this litigation.

Procedurally, the Court cannot determine the extent of overlap between the damages awarded in Andersen and the damages Edwards seeks in the current litigation until after final resolution of Medtronic's objections to Edwards' accounting submissions in Andersen, and final resolution of Medtronic's opposition based on Edwards' patent term extension request.

In the event lost profits are ultimately awarded in this litigation, and once the amount of any such award is determined, the amount of that award must be altered or amended to exclude damages awarded for the same sales in the Andersen litigation.

/s/ David M. Fry

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
David M. Fry (No. 5486)
SHAW KELLER LLP
300 Delaware Avenue, Suite 1120
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
dfry@shawkeller.com
Attorneys for Medtronic CoreValve LLC, Medtronic CV Luxembourg S.a.r.l., Medtronic Vascular Galway Ltd., Medtronic, Inc., and Medtronic Vascular, Inc.

OF COUNSEL:
Martin R. Lueck
Jan M. Conlin
Stacie E. Oberts
Munir R. Meghjee
Andrew D. Hedden
ROBINS, KAPLAN, MILLER & CIRESI LLP
2800 LaSalle Plaza
Minneapolis, MN 55402-2015
(612) 349-8500

Edward R. Reines
WEIL, GOTSHAL & MANGES LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065
(650) 802-3000

Dated: February 12, 2014